

# Developing



# Materials For GENETIC TESTING

D. Joe Boone, Ph.D

Division of Laboratory Systems

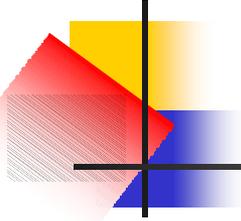
<http://www.phppo.cdc.gov/dls/genetics>

October 6, 2003



Department of Health and Human Services  
Centers for Disease Control and Prevention



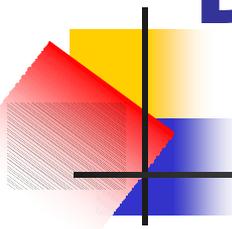


# **Reason for the Conference**

## **September 15-16, 2003**

---

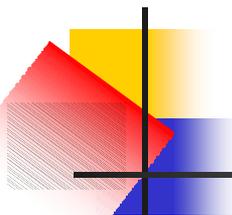
- **Lack of appropriate positive materials for genetic tests to provide:**
  - Quality Control
  - External Quality Assessment/Proficiency Testing
  - Developers of Genetic Tests



# Developing a Sustainable Process

---

- How can QC/PT Materials for genetic tests be obtained or developed?
- How can QC/PT materials be validated?
- How can QC/PT Materials be collected and stored?
- How can QC/PT materials be distributed at a reasonable cost ?

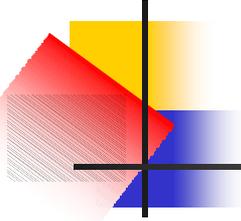


# **Conference Agenda**

## **September 15-16, 2003**

---

- Current QC Materials for Genetic Tests
- Research to Develop Materials for QC/PT
- Unmet and future needs?
- Applicability of research to address needs?
- Practical issues – validation and cost
- Bridging the gaps and sustaining a process

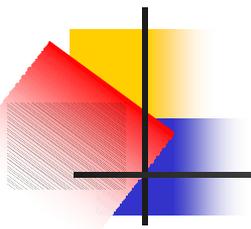


# Summary 1

---

**Materials can be obtained and can be made available at a reasonable cost**

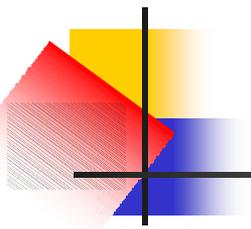
- Develop better collaboration among research community
- Develop better coordination of funding
- Develop guidance on appropriate QC
- Clarify regulatory requirements for producers of QC materials



## Summary 2

---

- Develop validation processes for QC materials
- Develop processes to use existing cell banks as sources for materials
- Develop a scheme to set priorities for materials
- Develop network of contributors of materials

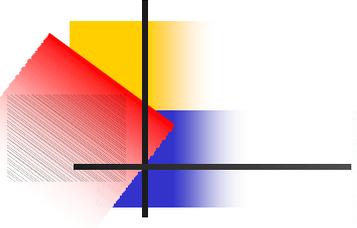


# Next Steps

---

- Assigned workgroups to address each bulleted item
- Workgroup leaders will form a steering committee to coordinate activities
- Next meeting planned for March 2004 in Orlando, Florida to review workgroup progress

# QC - steep climb – but achievable goal





Department of Health and Human Services  
Centers for Disease Control and Prevention

